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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,368	12/11/2001	Alex Wah Hin Yeung	506822000100	2730

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/04/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,368

Applicant(s)

YEUNG, ALEX WAH HIN

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

APPLICANT'S INVENTION

1. Applicant's invention is directed to a method of treating a disease in a subject by administering a positron emitting compound comprising one or more atoms of fluorine-18, carbon-11, nitrogen-13, or oxygen-15.

Note: Claims 1-20 are pending.

112 REJECTIONS

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-20: The claims as written are ambiguous because it is unclear what 'disease' the claims are directed to. In particular, it is unclear what disease the subjects are being treated for. Applicant is respectfully requested to clarify the claims and point to page and line numbers for support of which diseases the instant invention reads upon.

Claim 13, line 22: The claim as written is ambiguous because of the phrase 'other chemotherapy or radiation therapy'. In particular, it is unclear what additional chemotherapy/radiation therapies Applicant is intending to be compatible with the instant invention. Applicant is respectfully requested to clarify the claims and point to

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page and line numbers for support of the terminology 'other chemotherapy or radiation therapy'.

102 REJECTIONS

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1, 9-12, 13, 14, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by McPherson et al (US Patent No. 4,874,600).

McPherson et al disclose ¹¹C-putrescine and its use with positron emission tomography (see entire document, especially, abstract). The radiolabeled compound is useful for quantifying tumor growth rate in human brains and for monitoring response to radiotherapy and chemotherapy (columns 1-2, bridging paragraph). In mice studies, ¹¹C-putrescine (0.05-0.20 micro Curies/mouse) was injected by tail vein into mice at time intervals of 5, 30, and 60 minutes (column 4, Example 2). Thus, both Applicant

and McPherson et al disclose the use of a positron emitting compound comprising carbon-11.

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al (The Breast, 1999, Vol. 8, pages 303-310).

Smith et al disclose positron emission tomography imaging in breast disease. In addition, Smith et al discloses that positron emission tomography may be used to determine the lymph node status of patients with breast cancer and to predict and evaluate tumour response to chemotherapy (see entire document, especially, 'Summary'; page 305, columns 1-2; page 308, columns 1-2; page 308, Figure 2). On page 304, Table 1, various examples of radiopharmaceutical used for positron emission tomography are disclose. The radiopharmaceuticals include 2-[18F]fluoro-2-deoxy-D-glucose, [15O]water, [15O]oxygen, [11C]methionine, and [13N]glutamate to name a few. Thus, both Applicant and Smith et al disclose a method of treating a disease using a positron emitting tomography compound comprising fluorine-18, carbon-11, nitrogen-13, and oxygen-15.

7. Claims 1-4, 7-14, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Paulus et al (Acta Gastroenterol. Belg., 1997, Vol. 60, pages 278-280).

Paulus et al disclose the use of 18-fluorodeoxyglucose in the detection and follow-up of digestive cancers. In addition, Paulus et al disclose that the quantitative assessment of therapeutic response to chemotherapy is a promising application of

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positron emitting tomography (see entire document, especially, abstract). Also, Paulus et al disclose that it is normally recommended to use 100-400 MBq, but that typically 300 MBq in an adult patient being studied is used (page 279, column 1, second paragraph). Furthermore, Paulus et al disclose that [18F]fluorodeoxyglucose has been proven useful in the differentiation of pancreatic carcinoma versus mass forming pancreatitis and cites a reference wherein 2[18F]fluoro-2-deoxy-D-glucose is used (page 279, column 1, third paragraph). Thus, both Applicant and Paulus et al disclose a method of treating a disease using a positron emitting tomography compound comprising fluorine-18.

8. Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Schelbert (Cardiology Clinics, 1994, Vol. 12, No. 2, pages 303-315).

Schelbert discloses various assay techniques available through positron emitting tomography and how they aid in the diagnosis and management of cardiovascular disease (page 303, column 1, first paragraph). In addition, Schelbert discloses a series of different amino acids labeled with N-13 or C11, and in some instances, F-18 may be used or O-15 (page 304, column 2, first complete paragraph; page 307, column 1, third complete paragraph; page 309, column 2, second complete paragraph). Thus, both Applicant and Schelbert disclose a method of treating a disease using a positron emitting tomography compound comprising fluorine-18, carbon-11, nitrogen-13, and oxygen-15.

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103 REJECTIONS

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (US Patent No. 4,665,897).

Lemelson discloses the improvements in methods for treating diseases and tumor with a composition that may include monoclonal antibodies which may be combined with radionuclides such as carbon-11 or nitrogen-13 (see entire document, especially, abstract; column 8, lines 36-57; column 10, lines 61; columns 11-12, bridging paragraph; column 13, lines 5-18).

Thus, both Applicant and Lemelson disclose the use of compounds comprising carbon-11 or nitrogen 13 which may be used for treating a disease wherein the nuclide contains positron particles.

COMMENTS/NOTES

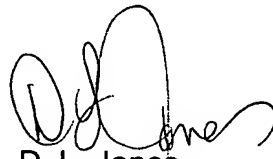
11. It is noted that prior art was not cited against claims 5,6, 15-18, and 20. However, in order for the claims to be distinguished over the prior art, Applicant needs to address and overcome the 112 rejection above clarify what disease the claims read upon.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones
Primary Examiner
Art Unit 1616

August 28, 2002